SW

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,207	08/28/2003	Aaron W. Janke	279.093US3	9733

7590 12/01/2004

Schwegman, Lundberg,
Woessner & Kluth, P.A.
P.O. Box 2938
Minneapolis, MN 55402

EXAMINER	
EVANISKO, GEORGE ROBERT	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/650,207	JANKE ET AL.
	Examiner	Art Unit
	George R Evanisko	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/27/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Information Disclosure Statement

The information disclosure statement filed 9/27/04 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because reference EP-0452278A2 is not a complete copy. It has been placed in the application file, but the information referred to therein for that reference has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Altman (5551427). Altman shows in figures 8 and 9 the use of an insulative drug on a helix and movement of the helix along the radial axis.

Claims 9, 13, and 14 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hoffmann et al (5902329).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janke et al (6097986).

Janke discloses the claimed invention except for the helix having an insulating coating with an active ingredient, such as an anti-inflammatant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Janke, with a helix having an insulating coating with an active ingredient, such as an anti-inflammatant since it was known in the art that heart leads use a helix having an insulating coating with an active ingredient, such as an anti-inflammatant, to allow the electrical properties of the helix to be changed and to include an active ingredient in the insulation to reduce irritability and inflammation of the helix.

Claims 1-5 and 7-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bisping (4886074).

Bisping discloses the claimed invention in figures 1-5 with electrode, 3, guiding mechanism, 8, movement assembly, 5, 9, and 3, with piston, 5, base, 3, knob, 9 or 12, slot, 10 or 11a, and helix, 7, except for the mesh screen disposed on the electrode tip and the helix having an insulating coating with an active ingredient, such as an anti-inflammatant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Bisping, with a mesh screen disposed on the electrode tip and the helix having an insulating coating with an active ingredient, such as an anti-inflammatant since it was known in the art that heart leads use a mesh screen disposed on the electrode tip to allow fibrous connective tissue to intertwine with the screen to firmly secure the electrode and since it was known in the art for heart leads to use a helix having an insulating coating with an active ingredient, such as an anti-inflammatant, to allow the electrical properties of the helix to be changed and to include an active ingredient in the insulation to reduce irritability and inflammation of the helix.

Claims 1, 2, 3, and 7-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grassi (4624265).

Grassi discloses the claimed invention in figure 4 with electrode, 21, guiding mechanism, 20, movement assembly, 14 and 17, seal, 16, base, 17, and piston, 14 between seals 16, and helix, 15, except for the mesh screen disposed on the electrode tip and the helix having an insulating coating with an active ingredient, such as an anti-inflammatant. It would have been

obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Grassi, with a mesh screen disposed on the electrode tip and the helix having an insulating coating with an active ingredient, such as an anti-inflammatant since it was known in the art that heart leads use a mesh screen disposed on the electrode tip to allow fibrous connective tissue to intertwine with the screen to firmly secure the electrode and since it was known in the art for heart leads to use a helix having an insulating coating with an active ingredient, such as an anti-inflammatant, to allow the electrical properties of the helix to be changed and to include an active ingredient in the insulation to reduce irritability and inflammation of the helix.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grassi.

Grassi discloses the claimed invention except for the knob and slot mating with the knob to form a stop mechanism. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Grassi, with a knob and slot mating with the knob to form a stop mechanism since it was known in the art that heart leads use a knob and slot mating with the knob to form a stop mechanism to prevent the helix from being retracted further into the lead and causing damage to the lead.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-21 of U.S. Patent No. 6097986. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are narrower and meet the limitations of the broader application claims. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate an active ingredient on an insulating material on the fixation device since it was known in the art that fixation leads use insulation on the fixation device to change its electrical properties and since it was known to include an active ingredient in the insulation to prevent infection.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art cited with this action (and in the IDS) are several examples of many that show it is well known in the art to include insulation on a fixation helix, active ingredients on a fixation helix, and active ingredients in the insulation of a fixation lead/helix.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

George R Evanisko
Primary Examiner
Art Unit 3762
11/29/04

GRE
November 29, 2004